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**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

05C 6387

QT, Inc., an Illinois corporation,

Plaintiff,

v.

**Mayo Clinic Jacksonville, Mayo Clinic
Rochester, Mayo Foundation,
Mayo Clinic College of Medicine, and
Robert L. Bratton, M.D.**, individually

Defendants.

Case No. _____

JUDGE MORAN

JURY DEMANDED

**MAGISTRATE JUDGE
GERALDINE SOAT BROWN**

COMPLAINT

Plaintiff, QT, Inc. ("QT"), by its attorneys, for its Complaint against Mayo Clinic Jacksonville, Mayo Clinic Rochester, Mayo Foundation, Mayo Clinic College of Medicine, and Robert L. Bratton (collectively, "Mayo" or "Defendants"), states as follows:

NATURE OF THE ACTION

1. This is an action for injunctive relief and damages arising under commercial disparagement, common law fraud, tortious interference with prospective economic advantage, negligence, negligent misrepresentation, the Uniform Deceptive Trade Practices Act, and the Consumer Fraud and Deceptive Business Practices Act.

2. Since approximately 1996, QT has exclusively marketed and sold in the United States a product, known as the Q-Ray® Ionized Bracelet®, offering a natural, non-medical alternative to consumers seeking alternatives to traditional forms of medical treatment.

3. Defendants, economically concerned about the substantial and growing amount of money spent by consumers in the United States on alternative forms of medicine, embarked on a campaign to discredit and undermine QT and the Q-Ray®

Ionized Bracelet®. Defendants did so by knowingly disseminating and publishing malicious and false information about the Q-Ray® Ionized Bracelet®.

4. Defendants' misrepresentations and omissions have restrained and impaired QT's ability to market and sell the Q-Ray® Ionized Bracelet®, and have and continue to irreparably harm QT's goodwill and business relations with its clients and potential clients, resulting in substantial damages to QT.

THE PARTIES, JURISDICTION AND VENUE

5. QT, Inc. is an Illinois corporation with its principal place of business at 500 W. Algonquin Road, Mt. Prospect, Illinois.

6. Mayo Clinic Jacksonville, on information and belief, provides health care services in Jacksonville, Florida to patients from Florida and from other states, including Illinois. On information and belief, Mayo Clinic Jacksonville, by itself and as part of the Mayo Foundation and Mayo group of providers of health care services, transacts business in Illinois by advertising health care services to consumers in Illinois, including consumers in Cook County, Illinois.

7. Mayo Clinic Jacksonville has entered into one written contract (described below) that was substantially connected with Illinois in that the counter-part to the contract, QT, Inc., is an Illinois corporation and the products that were the subject of the contract were sold in Illinois and from Illinois sold to other states. Mayo Clinic Jacksonville and its employees and agents, including principal investigator, Robert L. Bratton, designed, administered, and supervised the clinical trials at issue in this Complaint. Mayo Clinic Jacksonville employees and agents, including principal investigator Robert L. Bratton, committed at least one tortious act within Illinois by disseminating in Illinois, the false and misleading statements which are the subject of this Complaint.

8. Mayo Clinic Rochester, on information and belief, provides health care services in Rochester, Minnesota to patients from Minnesota and from other states, including Illinois. On information and belief, Mayo Clinic Rochester, by itself and as part of the Mayo Foundation and Mayo group of providers of health care services, transacts business in Illinois by advertising health care services to consumers in Illinois, including consumers in Cook County, Illinois.

9. Mayo Clinic Rochester, through employees and agents in its department of statistics, provided statistical assistance and analysis to Mayo Clinic Jacksonville in connection with the clinical trial at issue in this Complaint. On information and belief, Mayo Clinic Rochester employees and agents committed at least one tortious act within Illinois by disseminating in Illinois, the false and misleading statements which are the subject of this Complaint.

10. Mayo Foundation has its principal place of business in Rochester, Minnesota. In 2004, Mayo Foundation had revenues of approximately \$5.4 billion and realized a profit of \$305 million from its activities. At all times relevant to this case, Mayo Foundation represented itself to QT and the public as a leading institution providing professionally competent clinical research services. Mayo Foundation operates clinics and hospitals in three locations: Jacksonville, Florida; Rochester, Minnesota; and Scottsdale, Arizona. The Mayo Foundation also engages in clinical research programs. In 2004, Mayo Foundation received total funding of \$528 million for research and education activities.

11. On information and belief, the Mayo Foundation through its operating entities, transacts business in Illinois by advertising health care services to consumers in Illinois, including consumers in Cook County, Illinois.

12. Mayo Clinic College of Medicine, on information and belief, sponsors the journal *Mayo Clinic Proceedings*. *Mayo Clinic Proceedings* is disseminated nationwide, including in Illinois. Mayo Clinic College of Medicine has committed at least one tortious act within Illinois by disseminating in Illinois, the false and misleading publications and statements that are the subject of this Complaint. Those false and misleading statements appeared in, among other places, *Mayo Clinic Proceedings*.

13. Upon information and belief, Robert L. Bratton, M.D. is a resident of Jacksonville, Florida. Dr. Bratton an Associate Professor, Department of Family Medicine, Mayo Clinic, Jacksonville, Florida. Dr. Bratton served as lead investigator in connection with the clinical trials at issue in this Complaint. Dr. Bratton committed at least one tortious act within Illinois by disseminating in Illinois, the false and misleading statements which are the subject of this Complaint. Dr. Bratton is being sued in his individual capacity.

14. This Court has jurisdiction of this case pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and is between citizens of different states.

15. This Court has jurisdiction over Defendants for the reasons noted in this Complaint and because Defendants and each of them caused the injuries complained of in this Complaint, in this district.

16. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) because the claims asserted arise from actions that occurred in this District and Defendants are subject to personal jurisdiction in this district.

FACTS COMMON TO ALL COUNTS

17. QT, Inc. is a nationally and internationally known exclusive distributor of the Q-Ray® Ionized Bracelet® in the United States and worldwide. The Q-Ray®

Ionized Bracelet® had been sold in the United States since approximately 1996 and has been purchased by hundreds of thousands of satisfied customers.

18. Prior to September 1999, Robert L. Bratton, M.D., then a consultant in the Department of Family Medicine at the Mayo Clinic Jacksonville and assistant professor of family medicine at the Mayo Medical School, contacted QT and persuaded QT to permit Mayo Clinic Jacksonville and Dr. Bratton to conduct a clinical trial evaluating the efficacy of the Q-Ray® Ionized Bracelet®.

19. Prior to September 1999, QT already had tens of thousands of testimonials from satisfied customers and a number of successful clinical trials that evaluated and demonstrated the efficacy of the Q-Ray® Ionized Bracelet® for among other things, the reduction of muscle and joint pain. However, QT was aware that Mayo publicly claimed to be committed to conducting clinical research pursuant to the highest standards of ethics and quality, and QT agreed to have Mayo Clinic conduct another clinical trial.

20. In or about September 1999, Mayo Clinic Jacksonville entered into a written agreement with QT pursuant to which Mayo Clinic Jacksonville undertook to conduct a clinical trial, involving a total of 610 subjects, to evaluate the benefits of the Q-Ray® Ionized Bracelet® (the "First Study"). The First Study was to begin in October 1999 and was expected to conclude in November 1999.

21. Pursuant to the written agreement for the First Study, QT was to provide a total of 610 Q-Ray® Ionized Bracelets® for the First Study.

22. Prior to providing Q-Ray® Ionized Bracelets® for the First Study, QT informed Dr. Bratton and others at Mayo Clinic Jacksonville that the bracelets to be used by Mayo for the control group needed to be exposed (twice) by Mayo Clinic

Jacksonville to a hospital-grade x-ray machine in order to assure that the bracelets given to participants in the control group were deactivated bracelets.

23. Exposure to a hospital-grade x-ray machine was recommended by the Spanish manufacturer of the Q-Ray® Ionized Bracelet®. Such exposure had previously been used to create control groups in prior clinical trials involving the ionized bracelet.

24. This was well known to Mayo. In designing the First Study, Dr. Bratton, as Principal Investigator, prepared a written study protocol. That protocol included as an exhibit, a copy of an earlier clinical study performed in Korea ("Korean Study"). The Korean Study clearly stated that the bracelets used in the control group were subjected to an x-ray machine two times.

25. In or about April 2000, after approximately 540 people became enrolled and began participating in the First Study, Mayo Clinic Jacksonville abruptly suspended and then terminated the First Study.

26. On information and belief, among other things, the First Study was terminated because Dr. Bratton and his colleagues had virtually no prior clinical research experience and were not properly supervised by Mayo Clinic Jacksonville and Mayo's Institutional Review Board.

27. On information and belief, among other things, Dr. Bratton and his colleagues failed to follow the Mayo and Federal informed consent guidelines and regulations pertaining to clinical research.

28. In fact, not only did Dr. Bratton and his colleagues fail to follow Mayo and Federal guidelines, the Mayo Institutional Review Board determined, on information and belief, that Dr. Bratton and other investigators in the First Study were not properly trained in the conduct of clinical trials. When the First Study was

suspended, an Executive Subcommittee of the Mayo Institutional Review Board required Dr. Bratton and other investigators in the First Study to complete the Mayo Investigator Education Program as soon as possible.

29. After the First Study was terminated, Dr. Bratton and Mayo Clinic Jacksonville contacted participants in the First Study and falsely informed those participants that the First Study was terminated due to "logistical" reasons.

30. When the First Study was terminated by Mayo Clinic, Mayo Clinic did not disclose to QT that the First Study was terminated due to the incompetence of the investigators involved in the First Study and for violations of both Mayo Clinic Jacksonville and Federal guidelines and laws.

31. After the First Study was terminated, Mayo Clinic Jacksonville did not amend the written agreement nor enter into a new agreement with QT to permit Mayo Clinic Jacksonville to conduct a second trial. Instead, Mayo Clinic Jacksonville undertook, without any agreement, to conduct a second trial to evaluate the effectiveness of the Q-Ray® Ionized Bracelet® ("Second Study").

32. Although Dr. Bratton and Mayo Clinic Jacksonville represented to QT and in the written protocol for the Second Study that volunteers for the Second Study would be recruited via local newspapers and by placement of flyers on golf courses, this was never done. Instead, and contrary to both the written protocol as well as well-established proper clinical practices, the "volunteers" for the Second Study were principally Mayo Clinic Jacksonville's own employees. This fact was not disclosed to QT, nor to the public when Defendants later published and disseminated nationwide false and misleading statements concerning the results of the Second Study.

33. As QT had done in connection with the First Study, QT informed Dr. Bratton and others at Mayo Clinic Jacksonville that the bracelets used for the control

group in the Second Study needed to be exposed (twice) by Mayo Clinic Jacksonville to a hospital-grade x-ray machine in order to assure that the bracelets given to participants in the control group were deactivated bracelets.

34. As described below, by the time Dr. Bratton and his colleagues completed the Second Study, they had grossly and recklessly mismanaged the study design, study protocol, recruitment, informed consent, statistical analysis, and the administration of the Second Study. They had also published and disseminated across the United States and worldwide, false and misleading statements concerning the results of the Second Study.

35. Among other things, contrary to the instructions provided by QT concerning x-raying of the control group bracelets and contrary to Mayo Clinic including references to the x-raying within the protocol for the Second Study, Mayo Clinic Jacksonville never exposed the bracelets used in the control group to a hospital-grade x-ray machine in order to assure that the bracelets given to participants in the control group were deactivated bracelets.

36. Mayo Clinic Jacksonville has admitted that it failed to subject the control group bracelets to a hospital-grade x-ray machine prior to administering the Second Study.

37. Additionally, Dr. Bratton and his colleagues, among other things, failed to follow written procedures in the study protocol for the Second Study governing inclusion/exclusion criteria, failed to follow randomization procedures included in the study protocol, permitted volunteers to join the study knowing that the volunteers could not comply with the requirements of the study, permitted volunteers who violated the inclusion/exclusion criteria to participate in the study, recruited mostly Mayo Clinic Jacksonville employees in direct violation of Mayo Clinic Jacksonville's

own guidelines on conducting research using employees and their families, permitted people who had participated in the First Study to join the Second Study notwithstanding the fact that the participants of the First Study had already been told whether they had an activated or placebo bracelet, negligently, recklessly, and intentionally modified and changed study questionnaire data after the data had already been submitted to influence the results of the Second Study, improperly included data in the Second Study that was gathered in the First Study, omitted material information concerning non-compliance that would have revealed substantial defects in the study design and conclusions, and grossly misrepresented the results of the Second Study.

38. The Second Study was so grossly mismanaged by Mayo Clinic Jacksonville and Dr. Bratton that the clinical coordinator for the study, who had little prior clinical research/coordination experience before becoming the coordinator for the Second Study, was removed from her position shortly after the Second Study concluded and transferred to a department within Mayo Clinic Jacksonville that had nothing to do with clinical research.

39. Dr. Bratton and his colleagues knowingly completed and maintained as part of the Mayo Clinic Jacksonville research regulatory files numerous files that contained false information concerning the administration of the Second Study, including materials that misrepresented: the informed consent process for the study, randomization procedures, and statistical analysis and data cleanup procedures used in the Second Study. This information was known to Defendants but not disclosed when Defendants published and disseminated across the United States and worldwide, false and misleading statements concerning the results of the Second Study.

40. After the raw data was gathered and improperly and falsely manipulated, Dr. Bratton and his colleagues prepared a written report concerning the Second Study. Although QT requested to see a draft of the written report in order to review the draft report and comment on any possible errors or omissions, the written report was never shown to QT prior to publication.

41. The written report was published and distributed in November 2002, in *Mayo Clinic Proceedings* (a journal available in print and on the Mayo website), under the title "Effect of 'Ionized' Wrist Bracelets on Musculoskeletal Pain: A Randomized, Double-Blind, Placebo-Controlled Trial" ("Mayo Article"). A true and correct copy of the Mayo Article is attached as Exhibit A hereto.

42. *Mayo Clinic Proceedings* is a monthly journal sponsored and published by the Mayo Clinic College of Medicine on the subjects of clinical and laboratory medicine, clinical research, basic science research and clinical epidemiology. On information and belief, the November 2002 issue of the Mayo Clinic Proceedings journal was sent to approximately 130,000 subscribers worldwide and was available to thousands of additional readers. On information and belief, the content of the *Mayo Clinic Proceedings* journal is covered by all major abstracting and indexing services.

43. In addition to publishing and distributing the Mayo Article, Defendants issued, on November 12, 2002, a press release summarizing the conclusions of the Mayo Article ("Press Release"). A true and correct copy of the November 12, 2002 press release is attached as Exhibit B hereto.

44. Following the Press Release and the Mayo Article, Defendants produced Defendants' employees, including Dr. Bratton, for interviews with print, television, and radio media from across the United States, including media from Illinois, concerning

the conclusions of the Second Study, as reported in the Press Release and the Mayo Article.

45. The Mayo Article and Press Release contained a series of false statements about the Q-Ray® Ionized Bracelet®, including multiple statements that questioned the benefits of "using an ionized bracelet". The Mayo Article and Press Release also contained material misstatements and omissions concerning the Second Study, as detailed below.

46. Although Dr. Bratton concluded, based on the Second Study, that the use of ionized bracelets for the treatment of muscle and joint pain is beneficial, the conclusions printed in the Mayo Article and Press release falsely claimed that wearing ionized bracelets for the treatment of muscle and joint pain was no more effective than wearing placebo bracelets.

47. The Mayo Article and Press Release claimed that 610 people participated in the Second Study. That statement was false. Twenty-eight people were not-compliant and failed to participate in the study. This information was material to the reported results because it substantially impacted whether the study population was adequate. In fact, by withholding information that twenty-eight people failed to participate in the Second Study, Defendants gave the misimpression that the Second Study had a sufficient number of people to evaluate the results of the study when, in fact, that was untrue.

48. The Mayo Article and Press Release failed to disclose that most of the participants in the Second Study were employees of Mayo Clinic Jacksonville. This information was withheld because, on information and belief, Dr. Bratton and his colleagues failed to follow established regulations concerning using Mayo Clinic employees and families in clinical research.

49. The Mayo Article and Press Release falsely claimed that participants self-reported pain scores over a period of 28 days. In fact, participants were deemed to have completed the Second Study if they had reported results for only 14 days. On information and belief, there were substantial numbers of study participants in the Second Study for whom data for the full 28 days was never submitted.

50. Defendants hoped for and intended, on information and belief, that the Mayo Article generate significant national publicity for Defendants and that such publicity would help, among other things, sell more copies (and subscriptions) of the *Mayo Clinic Proceedings* journal.

51. To make the Mayo Article appear more authoritative and credible, and therefore, more interesting to the popular press, Dr. Bratton and his co-authors copied entire paragraphs of scientific writing of other scientists without properly crediting those other scientists. In doing so, Dr. Bratton and his co-authors not only claimed as their own the writings of other scientists, but also falsely misrepresented the conclusions of some of the other scientists.

52. Additionally, to make the Mayo Article appear more authoritative and credible, and therefore, more interesting to the popular press, Dr. Bratton and his co-authors either recklessly disregarded the truth and/or intentionally tried to undermine the credibility of an effective alternative medical therapy. They did so by incorporating in the Mayo Article, as discussed in this Complaint, conclusions and statements concerning the Q-Ray® Ionized Bracelet® that were false and grossly deficient.

53. Defendants' malicious misrepresentations were not isolated to a few employees of Defendants. Defendants' misconduct went to the highest levels, and on information and belief, included efforts by members of Mayo's Institutional Review

Board to cover-up the grossly deficient, reckless and/or fraudulent conduct of Mayo's clinical researchers that ultimately led to publication and dissemination of false and grossly deficient statements and conclusions concerning the Q-Ray® Ionized Bracelet®.

54. Following the publication of the Mayo Article, QT complained to Mayo explaining that the Mayo Article was based on a study that was improperly conducted by Mayo. QT complained that Mayo's inclusion of the Mayo Article in an official Mayo publication was an unfair and inappropriate measure of the efficacy of the Q-Ray® Ionized Bracelets® for the treatment of musculoskeletal pain.

55. In flagrant disregard to QT's concerns over Mayo's improper testing protocol as more fully described in this Complaint, Mayo physicians, including the principal investigator for the Mayo Article, Robert L. Bratton, not only republished the earlier false statements, but also asserted additional new false statements concerning the Q-Ray® Ionized Bracelets® in numerous interviews given to radio, television, print, and online media nationwide.

56. Mayo and its researchers have engaged in a pattern of denunciatory commentary directed against QT's Q-Ray® Ionized Bracelets®, by attacking the Q-Ray® Ionized Bracelets®.

57. Mayo's misconduct was exacerbated by rampant conflicts of interest in the clinical research involving the Q-Ray® Ionized Bracelets®. The Mayo Article was designed to give the appearance of an independent, clinical trial that incorporated the gold-standard for clinical research – a double, blind, placebo controlled, randomized trial. The Second Study however, was designed from the outset to be cursory in scope and the senior members of Mayo continuously ignored material deviations from study protocol during the clinical study. The Mayo Article grossly and recklessly

misrepresented the results of the Second Study and withheld material information. The Mayo Article did not truly report results from a double blind, placebo controlled, randomized trial. It was a fraud.

58. Defendants made the misrepresentations and omissions described herein with actual malice. At the time the statements were made, Defendants knew the statements to be false, or made the statements with reckless disregard as to their truth or falsity.

59. Although Mayo's conduct was a surprise to Plaintiff, it is evident that Mayo has engaged in a pattern of repeatedly failing to adhere to established clinical research standards and procedures. For example, in 2005, a former accounting associate in the Mayo Foundation Research Accounting Department filed a *qui tam* action alleging that Mayo misspent millions of dollars in Federal research grants over more than a decade. On May 26, 2005, Mayo agreed to pay \$6.5 million in penalties and fines, including \$1.3 million to the researcher who uncovered the fraud by Mayo.

60. As a result of Mayo's false and disparaging statements, QT has suffered substantial monetary damages in the form of a decline in sales of the Q-Ray® Ionized Bracelet®, harm to reputation and goodwill inflicted on both the company and the Q-Ray® Ionized Bracelet®, and interference with QT's prospective economic advantage. Mayo's pattern of wrongful conduct justifies full compensatory damages, special statutory damages, significant punitive damage awards, as well as recovery of QT's attorneys' fees and costs.

COUNT I - Commercial Disparagement

61. QT hereby incorporates and realleges all of the foregoing allegations of paragraphs 1 to 60 of this Complaint.

62. The above described false and misleading representations of fact constitute commercial disparagement in that they constitute false and misleading misrepresentations of fact which disparage QT and the Q-Ray® Ionized Bracelet®.

63. The above-described false and misleading representations of fact have caused and will continue to cause, unless enjoined, QT to suffer special damages from continued lost sales, harm to reputation and goodwill, and/or prospective business relations.

64. Defendants' misrepresentations and each of them as alleged in this Complaint were willful and QT is entitled to punitive damages as a result of such statements.

COUNT II – Tortious Interference With A Prospective Economic Advantage

65. QT hereby incorporates and realleges all of the foregoing allegations of paragraphs 1 to 60 of this Complaint.

66. At all times relevant, QT had an expectation of economic advantage with current and prospective customers. A consumer's decision to buy a particular product is based not only on the information provided by the seller of the product, but also on other pertinent information available to consumers.

67. Defendants, at all times relevant, knew of QT's relationship with its current and prospective customers for the Q-Ray® Ionized Bracelet®, and of QT's reasonable expectation that QT would profit therefrom.

68. Defendants' publications, republications, and statements of its employees and agents concerning QT and the Q-Ray® Ionized Bracelet® were and are disparaging and have misled or are likely to mislead or to deceive consumers as to the efficacy of the Q-Ray® Ionized Bracelet®.

69. Moreover, Defendants knew their actions were likely to interfere with QT's economic relationships with existing and prospective customers, and deliberately published false and disparaging statements in order to effectuate such interference.

70. Defendants' interference with QT's business relations was not privileged.

71. As a direct and proximate result of Defendants' wrongful interference, QT's relations and goodwill with consumers and practitioners of traditional and non-traditional forms of medicine throughout the United States has been damaged and QT has lost sales and profits. Additionally, Defendants' willful conduct and the need to deter future misconduct by Mayo and others, warrants an award of punitive damages in an additional amount to be determined at trial.

COUNT III - Uniform Deceptive Trade Practices Act

72. QT hereby incorporates and realleges all of the foregoing allegations of paragraphs 1 to 60 of this Complaint.

73. At all times relevant and material hereto, the states in which Defendants made their misrepresentations had adopted a version of the Uniform Deceptive Trade Practices Act.

74. The Uniform Deceptive Trade Practices Act provides that a person engages in a deceptive trade practice, when, in the course of his or her business, vocation or occupation, the person disparages the goods, services, or business of another by false or misleading representation of fact; or engages in any other conduct which similarly creates a likelihood of confusion or misunderstanding.

75. By way of example, in Illinois, pursuant to the Illinois Uniform Deceptive Trade Practices Act, 815 ILCS 510/1 et seq., Defendants' false statements about the Q-Ray® Ionized Bracelet® are deceptive trade practices because they "disparage the goods, services, or business of another by false or misleading representations of fact."

76. Defendants' intentional promotion and dissemination of the aforementioned false and misleading information misrepresents the nature, characteristics and qualities of the Q-Ray® Ionized Bracelet® in violation of the Uniform Deceptive Trade Practices Act, as in effect in those states where Defendants made their false representations.

77. Defendants' wrongful conduct has caused and will continue to cause substantial and irreparable harm and injury to QT, and QT seeks injunctive relief restraining Defendants from making any further false and misleading statements regarding the Q-Ray® Ionized Bracelet®.

78. Defendants' statements and each of them as alleged in this Complaint were willful and QT is entitled, in addition to all other relief, attorneys fees and costs under the Uniform Deceptive Trade Practices Act, as in effect in those states where Defendants made their false representations.

COUNT IV - Consumer Fraud And Deceptive Business Practices Act

79. QT hereby incorporates and realleges all of the foregoing allegations of paragraphs 1 to 60 and paragraphs 72 to 78 of this Complaint.

80. At all times relevant and material hereto, the states in which Defendants made their misrepresentations had adopted a version of the Consumer Fraud and Deceptive Business Practices Act.

81. The Consumer Fraud and Deceptive Business Practices Act provides that unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentations or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or submission of such material fact, or the use of employment of any practice described

in the Uniform Deceptive Trade Practices Act in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby.

82. Defendants' false statements about the Q-Ray® Ionized Bracelet® are deceptive trade practices because they "disparage the goods, services, or business of another by false or misleading representations of fact."

83. Defendants' intended that consumers and others rely on the aforementioned false and misleading information disseminated by Defendants.

84. The deceptive acts and practices occurred in the course of conduct involving trade or commerce. As providers of traditional medical services, Defendants are in direct competition with the Q-Ray® Ionized Bracelet®, which offers a natural alternative to certain consumers.

85. Defendants' wrongful conduct has caused and will continue to cause substantial and irreparable harm and injury to QT, and QT seeks injunctive relief restraining Defendants from making any further false and misleading statements regarding the Q-Ray® Ionized Bracelet®.

86. As a direct and proximate result of Defendants' misrepresentations, acts and practices, QT has lost sales and profits and has suffered damages to its goodwill and reputation and the goodwill and reputation of its Q-Ray® Ionized Bracelet®.

87. Additionally, Defendants' willful conduct and the need to deter future misconduct by Mayo and others, warrants an award of punitive damages in an additional amount to be determined at trial.

88. Defendants' statements and each of them as alleged in this Complaint were willful and QT is entitled, in addition to all other relief, attorneys fees and costs

under the Consumer Fraud and Deceptive Business Practices Act, as in effect in those states where Defendants made their false representations.

COUNT V - Common Law Fraud

89. QT hereby incorporates and realleges all of the foregoing allegations of paragraphs 1 to 60, paragraphs 72 to 78, and paragraphs 79 to 88 of this Complaint.

90. Defendants are engaged, among other things, in the business of publishing, communicating, or causing to be published, test results and reports on a range of products used in the health care industry. Defendants are also in the business of evaluating, testing, or causing to be tested or evaluated various products used in the health care industry, and selecting standards, methodologies, and data assessment methods to perform such tests in clinical trials.

91. By issuing and publishing statements about the Q-Ray® Ionized Bracelet® without the approval and consent of QT, Defendants assumed a duty of reasonable care to provide true, accurate, complete, and reliable information.

92. Additionally, by issuing and publishing statements about the Q-Ray® Ionized Bracelet® without the approval and consent of QT, Defendants assumed a duty of reasonable care in conducting a clinical trial involving the Q-Ray® Ionized Bracelet® in an accurate, scientific, and reliable manner.

93. Through the exercise of reasonable care, Defendants knew or should have known that their publications, communications, and statements concerning the Q-Ray® Ionized Bracelet® were false and misleading.

94. Through the exercise of reasonable care, Defendants knew or should have known that their publications, communications, and statements concerning the Q-Ray® Ionized Bracelet® were inaccurate, non-scientific and unreliable.

95. Defendants breached their duty of care by failing to act reasonably in publishing, communicating, or causing to be published or communicated, their false and misleading statements and clinical research results concerning the Q-Ray® Ionized Bracelet®.

96. In publishing, communicating, and causing to be published or communicated, the false and misleading statements and clinical research results concerning the Q-Ray® Ionized Bracelet®, as described above, Defendants intended that consumers who read the statements and publications rely on Defendants' statements and publications.

97. Consumers who read the statements and publications of Defendants concerning the clinical research results involving the Q-Ray® Ionized Bracelet® assumed that such statements and publications were truthful, complete and accurate.

98. To the contrary, Defendants' publications, republications, and statements concerning QT and the Q-Ray® Ionized Bracelet® were and are disparaging and have misled or are likely to mislead or to deceive consumers as to the efficacy of the Q-Ray® Ionized Bracelet® for the treatment of muscle and joint pain.

99. As a direct and proximate result of Defendants' misrepresentations, QT's relations and goodwill with consumers and practitioners of traditional and non-traditional forms of medicine throughout the United States has been damaged and QT has lost sales and profits.

100. Punitive damages are appropriate because of Defendants' recidivist conduct, their gross negligence, willful and wanton disregard of their obligations to the general public, willful and wanton disregard of their obligations under the applicable federal statutes governing clinical research, and the need to punish and deter Defendants from future misconduct.

COUNT VI – Negligence

101. QT hereby incorporates and realleges all of the foregoing allegations of paragraphs 1 to 100 of this Complaint.

102. Defendants are in the business of, among other things, evaluating, testing, or causing to be tested or evaluated various products used in the health care industry, and selecting standards, methodologies, and data assessment methods to perform such tests in clinical trials.

103. Defendants are also engaged, among other things, in the business of publishing, communicating, or causing to be published, clinical test results and reports concerning products used in the health care industry.

104. By disseminating and publishing statements about the Q-Ray® Ionized Bracelet®, Defendants assumed a duty of reasonable care in conducting a clinical trial involving the Q-Ray® Ionized Bracelet® in an accurate, scientific, and reliable manner.

105. By disseminating and publishing statements about the Q-Ray® Ionized Bracelet®, Defendants also assumed a duty of reasonable care to provide true, accurate, complete, and reliable information.

106. Through the exercise of reasonable care, Defendants knew or should have known that their publications, communications, and statements concerning the Q-Ray® Ionized Bracelet® were inaccurate, non-scientific and unreliable.

107. Through the exercise of reasonable care, Defendants knew or should have known that their publications, communications, and statements concerning the Q-Ray® Ionized Bracelet® were false and misleading.

108. Defendants were negligent and breached their duty of care by failing to act reasonably in publishing, communicating, or causing to be published or

communicated, their false and misleading statements and clinical research results concerning the Q-Ray® Ionized Bracelet®.

109. As a direct and proximate result of Defendants' misrepresentations, QT's relations and goodwill with consumers and practitioners of traditional and non-traditional forms of medicine throughout the United States have been damaged and QT has lost sales and profits.

110. Punitive damages are appropriate because of Defendants' recidivist conduct, willful and wanton disregard of their obligations to the general public, willful and wanton disregard of their obligations under the applicable federal statutes governing clinical research, and the need to punish and deter Defendants from future misconduct.

COUNT VII – Negligent Misrepresentation

111. QT hereby incorporates and realleges all of the foregoing allegations of paragraphs 1 to 110 of this Complaint.

112. Defendants are in the business of supplying information for the guidance of others in their business relations with third parties. Specifically, Defendants are in the business of supplying information for the guidance of consumers of medical products and services in their business relations with providers of medical products and services. Additionally, Defendants are in the business of supplying information for the guidance of providers of medical products and services in their business relations with consumers of such products and services.

113. In the course of supplying information to guide consumers and providers of medical products and services, Defendants made negligent misrepresentations, as described in this Complaint, by publishing, communicating, or causing to be

published or communicated, false and misleading statements and clinical research results concerning the Q-Ray® Ionized Bracelet®.

114. As a direct and proximate result of Defendants' negligent misrepresentations, QT's relations and goodwill with consumers and practitioners of traditional and non-traditional forms of medicine throughout the United States have been damaged and QT has lost sales and profits.

115. Punitive damages are appropriate because of Defendants' recidivist conduct, willful and wanton disregard of their obligations to the general public, willful and wanton disregard of their obligations under the applicable federal statutes governing clinical research, and the need to punish and deter Defendants from future misconduct.

WHEREFORE, Plaintiff QT, Inc. requests that judgment be entered against the Defendants, jointly and severally, as follows:

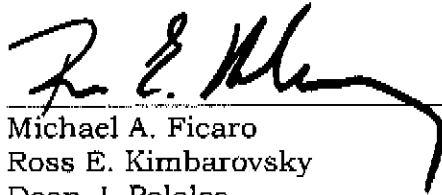
- A. An Order finding that Defendants have committed acts of commercial disparagement by issuing false and misleading publications, communications and statements concerning the Q-Ray® Ionized Bracelet®;
- B. An Order permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, successors and assigns, and all others in active concert with Defendants, from continued publication or republication of false and misleading statements concerning the Q-Ray® Ionized Bracelet®;
- C. An Order requiring Defendants to issue appropriate retractions and corrective statements with respect to their false and misleading statements about the Q-Ray® Ionized Bracelet®;
- D. An Order awarding QT, Inc. compensatory, punitive and special damages, interest and costs in amounts to be proven at trial;
- E. An Order awarding QT its attorney's fees; and
- F. Any other relief this Court deems just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a jury trial in this matter of all claims so triable.

Dated: November 8, 2005

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "R. E. Kimbarovsky", is written over a horizontal line.

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EXHIBIT A



Effect of "Ionized" Wrist Bracelets on Musculoskeletal Pain: A Randomized, Double-Blind, Placebo-Controlled Trial

ROBERT L. BRATTON, MD; DANIEL P. MONTERO, MD; KEVIN S. ADAMS, MD;
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MICHAEL B. MUELLER, DO; PETER C. O'BRIEN, PhD; ELIZABETH J. ATKINSON, MS; AND MEGAN S. MAURER, BS

• **Objective:** To assess objectively the perceived benefits of wearing an "ionized" wrist bracelet to treat muscle or joint pain.

• **Subjects and Methods:** This study was performed at the Mayo Clinic in Jacksonville, Fla, in 2000 and 2001. In a randomized, double-blind design, 305 participants wore an ionized bracelet and 305 wore a placebo bracelet for 4 weeks. For each location where pain was present at baseline, participants rated the intensity of pain. Follow-up ratings were made after 1, 3, 7, 14, 21, and 28 days of wearing the bracelet. Two primary end points were defined for evaluating efficacy. The first was the change at 4-week follow-up (day 28) in the pain score at the location with the highest baseline value (maximum pain score).

The second was the change at 4-week follow-up in the sum of the pain scores for all locations.

• **Results:** Analysis of the data showed significant improvement in pain scores in both groups, but no differences were observed between the group wearing the placebo bracelet and the group wearing the ionized bracelet.

• **Conclusion:** The finding that subjective improvement in pain scores was equivalent with ionized and placebo bracelet use questions the benefit of using an ionized bracelet. New treatments in alternative medical therapy must be shown to be effective through vigorous, unbiased, objective testing before physicians acknowledge potential benefits or recommend these treatments to patients.

Mayo Clin Proc. 2002;77:1164-1168

Treating pain involves multiple modalities. From medications to physical therapy and acupuncture, the options are numerous and varied. However, despite physicians' best efforts to provide pain relief, many patients continue to have pain. Increasingly, patients are trying unconventional treatments in place of traditional, evidence-based medical treatments. In fact, the interest in alternative medicine has grown considerably in recent years.^{1,2} A population-based survey³ indicated that 4 of 10 Americans used complementary and alternative medicine for chronic conditions in 1997 and made an estimated 629 million visits to practitioners of alternative medicine, far exceeding the 388 million visits that were made to primary care physicians during the same year. In addition, the total out-of-pocket expenditures related to the use of complementary and alternative medicine in 1997 were estimated at

\$27 billion, which is comparable to out-of-pocket expenditures for all physician services.^{3,4}

Many methods used in alternative medicine are insufficiently tested or not tested at all.⁵ Despite the enormous interest of the general public in alternative medical treatments, little evidence-based research supports claims about the efficacy of such methods. The reasons include lack of interest by the academic community, lack of financial support by corporate sponsors to fund research because the medications are already available, and difficulties in applying current regulatory criteria to alternative medicine.¹

One alternative method previously untested in the United States is the use of "ionized" wrist bracelets for pain relief. Promotional information from the manufacturer states that the ionized bracelet can "energize the whole body," "relieve pain the natural way," and balance "Yin & Yang (positive and negative ions)." According to the Yin-Yang theory, a relationship exists among acupuncture points, meridians, and the electric currents of the body. An electric current is generated by an interaction of positively and negatively charged ions. If the flow of energy called "chi" remains unimpeded and in balance, individuals are believed to remain physically and mentally balanced and therefore in peak health.⁶ According to the company's promotional information, the bracelets were invented by Dr Manuel Polo in 1973 in Spain. The "natural series" brace-

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lets used for this study were 85% copper and 15% zinc, and the cost was approximately \$50 each. More expensive models (up to \$179) are available from the manufacturer. The ionization process is a secret process not revealed by the manufacturer. A small study (50 patients) from China (not found in a review of the literature) reported benefit with use of the ionized bracelet for headache and for back, hip, leg, and hand pain over a 6-week period.⁶ Although numerous professional athletes such as golfers, basketball stars, weight lifters, and hockey players have given testimonials regarding the benefits, questions remain about the effectiveness of these bracelets in relieving pain. We performed a randomized double-blind trial to assess objectively the effects of these ionized wrist bracelets on musculoskeletal pain.

SUBJECTS AND METHODS

Volunteers were recruited from advertisements posted at the Mayo Clinic in Jacksonville, Fla, in 2000 and 2001. Participants included 610 men and women, 18 years of age or older, who had self-reported pain at the beginning of the study in at least 1 of the following areas: neck, shoulders, elbows, wrists, hands, upper back, mid back, lower back, hips, knees, ankles, or feet.

Both ionized and placebo bracelets were provided by the manufacturer. The appearance of each bracelet was identical. The identity of each bracelet was blinded to the manufacturer, participants, and researchers until the study was completed. Specific instructions were given to each participant for correct placement of the bracelets according to the manufacturer's recommendations. This study was approved by the Mayo Foundation Institutional Review Board, and participants gave informed consent.

Procedures

Participants were randomly assigned to receive either an ionized wrist bracelet (Q-Ray, QT, Inc, Elk Grove Village, Ill) (n=305) or a placebo wrist bracelet of identical appearance (n=305).

Demographic information, collected on all 610 participants in an initial questionnaire, included age, sex, ethnic background, whether the participant had ever seen or used an ionized bracelet, and whether the participant believed that such a bracelet would reduce joint or muscle pain. Participants were asked to indicate the area in which they had pain and whether they had had a serious injury at that site. For each location where pain was present, participants rated the intensity of the pain on a scale of 1 to 10, with 1 indicating "very little pain" and 10 indicating "pain as bad as it could be." A follow-up questionnaire was given to evaluate pain at these locations after participants wore the bracelets for 1, 3, 7, 14, 21, and 28 days. In this question-

naire, pain was rated on a scale from 0 to 10, with 0 indicating "no pain," 1 indicating "very little pain," and 10 indicating "pain as bad as it could be."

Primary End Points

For each location where pain was present at baseline, changes in pain score were calculated by subtracting the baseline score from the follow-up score at each time point. The percentage of patients whose pain score had improved was also calculated for each time point.

Two primary end points were defined for evaluating efficacy. The first was the change at 4-week follow-up (day 28) in the pain score at the location with the highest baseline value (maximum pain score). The second was the change at 4-week follow-up in the sum of the pain scores for all locations.

Statistical Analysis

Comparisons between groups were based on rank sum tests for quantitative variables and χ^2 tests for dichotomous variables. Tests about whether the percentage of patients with improvement exceeded 50% within each group were conducted at each time point with the use of a normal approximation to the binomial distribution.

All tests for efficacy were 1-sided because they addressed a 1-sided question. All other tests were 2-sided.

Stepwise linear regression was then applied to determine whether group allocation would become significant after adjusting for other factors. The end points used were the 4-week changes in the following scores: maximum pain score, sum of pain scores for all locations, and pain scores for the individual locations where pain had been reported at baseline. The possible confounding variables considered were participants' age, sex, racial origin, whether they had seen the bracelets before, whether they had used the bracelets before, whether they believed that the bracelets could reduce joint or muscle pain, whether they were taking medication for pain, and the magnitude of the baseline score. The significance level used as a criterion for entering and staying in the model was $P < .10$. "Group" was then added as a variable in the final model to determine whether there was a difference between those who wore the placebo bracelet and those who wore the ionized bracelet, after adjusting for all significant factors.

RESULTS

The mean age of the 609 participants who gave their age on the questionnaire was 48.27 years (SD, 13.46 years; range, 18-88 years). Of 608 participants who gave information on sex, 157 (25.8%) were male and 451 (74.2%) were female. Of 607 participants who gave information on racial origin,

Table 1. Baseline Demographic Variables and Previous Experience With Ionized Bracelets

Variable	Placebo* (n=305)	Ionized* (n=305)
Mean age (SD) (y)	48.4 (12.9)†	48.1 (14.0)†
Male	75/304 (24.7)	82/304 (27.0)
Racial origin other than white	41/303 (13.5)	33/304 (10.9)
Seen bracelets before	141/305 (46.2)	147/305 (48.2)
Used bracelets before	13/304 (4.3)	14/305 (4.6)
Believe bracelets work	163/195 (83.6)	164/214 (76.6)

*No. of subjects/no. of respondents (percentage).

†Of 305 placebo bracelet respondents and 304 ionized bracelet respondents.

533 (87.8%) were white and 74 (12.2%) were of other racial origin. Of 409 participants who answered the question about whether they believed the bracelets can reduce joint or muscle pain, 327 (80.0%) gave a positive and 82 (20.0%) a negative answer.

Comparisons at baseline between those who wore the placebo bracelet and those who wore the ionized wrist bracelet are summarized in Tables 1 through 3. The groups did not differ significantly from each other at baseline for any variable except elbow injury (Table 3). In view of the large number of statistical tests undertaken, some comparisons might have been expected to differ significantly by chance.

No significant differences were seen between groups for either of the primary end points, ie, change at 4-week follow-up in maximum pain score and in sum of pain scores for all locations. The groups did not differ in the magnitude of change in these variables at any time point during the study, although statistically significant de-

Table 3. Baseline Pain Scores for Locations Where Participants Reported Pain*

Site	Placebo (n=305)		Ionized (n=305)	
	No.†	Mean (SD) pain score	No.†	Mean (SD) pain score
Neck	174	4.9 (2.2)	166	4.7 (2.3)
Shoulders	182	5.0 (2.2)	177	5.1 (2.4)
Elbows	65	4.3 (2.2)	67	4.2 (2.3)
Wrists	109	4.8 (2.3)	103	4.5 (2.4)
Hands	118	5.1 (2.5)	116	4.8 (2.6)
Upper back	90	5.1 (2.1)	81	5.0 (2.5)
Mid back	86	4.9 (2.0)	89	5.3 (2.4)
Lower back	191	5.5 (2.2)	186	5.8 (2.3)
Hips	123	5.6 (2.3)	104	5.7 (2.5)
Knees	157	5.4 (2.4)	158	5.1 (2.6)
Ankles	65	5.0 (2.7)	70	5.0 (2.5)
Feet‡	123	5.7 (2.4)	122	5.0 (2.6)

*For each location where pain was present, participants rated the intensity of the pain on a scale of 1 to 10 (1 = very little pain; 10 = pain as bad as it could be).

†Number of participants reporting pain at an individual location.

‡Pain scores in ionized and placebo bracelet groups did not differ significantly from each other at any sites ($P > .05$) except feet ($P = .04$).

Table 2. Percentage of Participants Reporting Baseline Pain or Injury

Site	Placebo (%) (n=305)		Ionized (%) (n=305)	
	Pain	Injury	Pain	Injury
Neck	57.1	9.5	54.4	9.8
Shoulders	59.7	9.5	58.0	8.2
Elbows	21.6	3.6*	22.0	0.7*
Wrists	35.7	2.6	33.8	2.3
Hands	39.0	1.6	38.0	2.0
Upper back	29.5	3.6	26.6	2.3
Mid back	28.2	3.6	28.8	3.0
Lower back	62.3	11.5	61.0	10.2
Hips	40.3	2.0	34.4	2.3
Knees	51.8	9.5	51.8	6.9
Ankles	21.3	3.6	23.0	4.6
Feet	40.3	4.6	40.0	4.3

*Differences between ionized and placebo bracelet groups were not statistically significant ($P > .05$) except for elbow injury ($P = .01$).

creases from baseline were observed within each group at all time points (Figures 1 and 2). Similarly, no significant differences were seen between groups in the mean change from baseline after 4 weeks at any site where pain had been present at baseline, although significant decreases from baseline were observed within each group at each site (Table 4).

When the percentages of patients with improvement in maximum pain score or sum of pain scores for all locations were evaluated at each time point, we again saw no significant difference between groups, although within-group improvement rates were significantly greater than 50% in most instances (Table 5).

Analyses were also undertaken in which comparisons were made between groups after adjusting for other factors that may influence change in pain (eg, age). The results of regression analysis taking such factors into account are listed in Table 6. For each end point, the factors that were significantly ($P < .10$, see Subjects and Methods section) associated with change in pain scores were identified, and then treatment group was added to the regression model. In each case, no significant association with treatment was identified. This indicates that the failure to identify an effect from the ionized wrist bracelet beyond the effect available from placebo cannot be ascribed to other factors.

DISCUSSION

The results of this study suggest that the use of ionized bracelets for treating muscle and joint pain was no more effective for relieving musculoskeletal pain than was the use of placebo bracelets. However, both groups showed subjective improvement in pain scores.

Up to 30% to 40% of patients with a wide range of clinical conditions, such as pain, asthma, high blood pressure, and even myocardial infarction, have reported subjec-

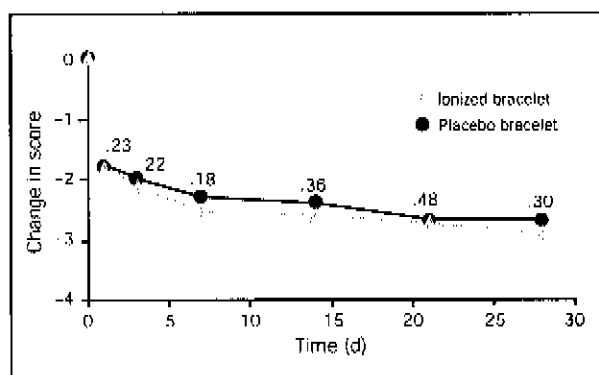


Figure 1. Changes in maximum pain score during 4 weeks of treatment with an ionized bracelet (triangles) or a placebo bracelet (circles). Numbers at data points represent *P* values of the differences between ionized and placebo bracelets.

tive improvement with the use of placebos. However, the effectiveness of placebos has been questioned recently. In an analysis of clinical trials comparing placebo with no treatment, Hróbjartsson and Gøtzsche⁷ found little evidence that placebos had powerful clinical effects except for "possible small benefits in studies with continuous subjective outcomes and for the treatment of pain." Additionally, therapeutic patterns that heighten placebo effects are especially prominent in unconventional healing, and this form of healing may have "enhanced" placebo effects in particu-

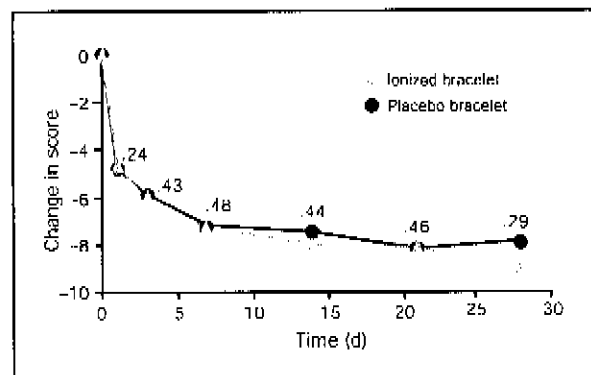


Figure 2. Changes in sum of pain scores during 4 weeks of treatment with an ionized bracelet (triangles) or a placebo bracelet (circles). Numbers at data points represent *P* values of the differences between ionized and placebo bracelets.

lar conditions.⁸ Although the goal of our study was not to assess the effectiveness of placebos, our results supported the benefits of using placebos to treat pain. The participants in both the ionized and the placebo bracelet group showed a subjective improvement in pain scores. This study did not include participants who received no bracelet. Such a group would have allowed us to study pain in an untreated group during the same period and could have strengthened the results of this study. Accordingly, it is unclear whether pain would have improved in similar

Table 4. Changes in Pain Scores at Individual Locations After 4 Weeks of Wearing Ionized or Placebo Bracelet*

Site	Placebo (n=305)		Ionized (n=305)	
	No.†	Mean‡ (SD) change in pain score	No.†	Mean‡ (SD) change in pain score
Neck	159	-1.4 (2.5)	158	1.7 (2.4)
Shoulders	164	-1.5 (2.6)	167	-2.0 (2.6)
Elbows	57	-1.3 (2.6)	64	-1.7 (2.5)
Wrists	98	1.9 (2.4)	95	-2.1 (2.5)
Hands	108	-1.8 (2.4)	111	2.1 (2.6)
Upper back	80	-1.6 (2.9)	76	-1.7 (2.7)
Mid back	70	1.4 (2.8)	79	-2.0 (2.6)
Lower back	175	-2.1 (2.6)	177	2.3 (2.7)
Hips	110	-2.2 (2.7)	94	-2.2 (3.1)
Knees	137	-2.1 (2.4)	150	-1.9 (2.6)
Ankles	59	2.5 (2.9)	64	-2.6 (2.7)
Feet	114	-2.3 (2.6)	116	2.2 (2.8)

*For each location where pain was present, participants rated the intensity of the pain on a scale of 0 to 10 (0 = no pain; 10 = pain as bad as it could be).

†Number of participants reporting pain at an individual site.

‡Differences between ionized and placebo bracelet groups were not statistically significant (*P* > .05). Mean changes within each group were significantly different from 0 at all time points (*P* < .05).

Table 5. Participants With Improved Maximum Pain Score and Sum of Pain Scores for All Locations During 4 Weeks of Treatment With Ionized or Placebo Bracelet

Time	Placebo (n=305)		Ionized (n=305)	
	No.* (%)†		No.* (%)†	
Patients with improved maximum pain score				
Day 1	209 (68.5)		193 (63.3)	
Day 3	219 (71.8)		228 (74.8)	
Day 7	229 (75.1)		231 (75.7)	
Day 14	237 (77.7)		234 (76.7)	
Day 21	236 (77.4)		230 (75.4)	
Day 28	234 (76.7)		236 (77.4)	
Patients with improved sum of pain scores				
Day 1	210 (68.8)		188 (61.6)	
Day 3	212 (69.5)		217 (71.2)	
Day 7	232 (76.1)		228 (74.8)	
Day 14	235 (77.0)		226 (74.1)	
Day 21	234 (76.7)		229 (75.1)	
Day 28	227 (74.4)		237 (77.7)	

*Number of participants who reported improvements.

†Differences between ionized and placebo groups were not statistically significant (*P* > .05). Response rates within each group were significantly greater than 50% (*P* < .05) except for the maximum pain score on day 1 with both ionized and placebo bracelets and for the sum of pain scores on day 1 with the ionized bracelet.

Table 6. Regression Models Analyzing Contribution of Predictor Variables to Change in Pain Scores After 4 Weeks of Treatment

Predictors	Coefficient (β)	SE	P value	Adjusted R ²	Predictors	Coefficient (β)	SE	P value	Adjusted R ²
Maximum pain score				0.130	Upper back				0.266
Bracelet type	-0.221	0.216	.31		Bracelet type	-0.098	0.383	.80	
Initial maximum score	0.456	0.051	<.001		Age	0.034	0.015	.02	
Age	0.025	0.008	.002		Initial pain	-0.617	0.083	<.001	
Sum of pain scores				0.182	Mid back				0.269
Bracelet type	-1.380	0.990	.16		Bracelet type	-0.347	0.386	.37	
Initial sum score	-0.337	0.030	<.001		Age	0.042	0.014	.003	
On pain medication	1.843	1.090	.09		Initial pain	-0.592	0.086	<.001	
Age	0.115	0.038	.002		Lower back				0.173
Neck				0.150	Bracelet type	-0.075	0.261	.77	
Bracelet type	0.344	0.257	.18		Age	0.030	0.010	.003	
On pain medication	0.535	0.265	.04		Initial pain	0.492	0.058	<.001	
Initial pain	-0.431	0.058	<.001		Hips				0.211
Shoulders				0.184	Bracelet type	-0.030	0.358	.93	
Bracelet type	0.300	0.261	.25		Age	0.037	0.014	.01	
On pain medication	0.734	0.269	.007		On pain medication	0.507	0.367	.17	
Initial pain	-0.474	0.057	<.001		Initial pain	-0.567	0.077	<.001	
Elbows				0.288	Knees				0.159
Bracelet type	-0.480	0.386	.22		Bracelet type	0.084	0.273	.76	
Age	0.040	0.017	.02		Age	0.040	0.011	<.001	
On pain medication	0.953	0.396	.02		On pain medication	0.289	0.284	.31	
Initial pain	0.538	0.085	<.001		Initial pain	-0.378	0.055	<.001	
Wrists				0.249	Ankles				0.277
Bracelet type	-0.405	0.308	.19		Bracelet type	0.240	0.433	.58	
Age	0.053	0.013	<.001		Age	0.047	0.017	.007	
Initial pain	-0.492	0.067	<.001		Initial pain	-0.591	0.086	<.001	
Hands				0.204	Feet				0.234
Bracelet type	-0.528	0.304	.08		Bracelet type	-0.377	0.318	.24	
Age	0.022	0.013	.08		Age	0.040	0.013	.003	
Initial pain	-0.466	0.061	<.001		Female	-0.233	0.387	.55	
					Initial pain	-0.501	0.063	<.001	

populations with observation alone. Further studies could help clarify this issue.

CONCLUSION

Alternative medical treatments are increasing in popularity. Although patients may perceive benefits from alternative medical therapies, there is little objective evidence to support the effectiveness of most alternative methods. Our finding that the subjective improvement in pain scores was similar for ionized and placebo bracelets questions the benefit of using an ionized bracelet. As practicing clinicians, we need continued research to test claims made by manufacturers of alternative medical products to ensure that our recommendations are adequately and sufficiently supported by objective, research-based evidence.

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EXHIBIT B

Mayo Clinic in Rochester

Tuesday, November 12, 2002

Study Concludes No Difference Between Ionized Bracelet and Placebo for Musculoskeletal Pain Relief

JACKSONVILLE, Fla., Nov. 8, 2002 — Researchers from Mayo Clinic in Jacksonville, Fla., report wearing ionized bracelets for the treatment of muscle and joint pain was no more effective than wearing placebo bracelets in the November 2002 issue of Mayo Clinic Proceedings.

Authors of the published study randomly assigned 305 participants to wear an ionized bracelet for 28 days and another 305 participants to wear a placebo bracelet for the same duration.

The study volunteers were men and women 18 and older who had self-reported musculoskeletal pain at the beginning of the study. Neither the researchers nor the participants knew which volunteers wore an ionized bracelet and which wore a placebo bracelet. Bracelets were worn according to the manufacturer's recommendations. Both types of bracelets were identical and were supplied by the manufacturer, Q1, Inc.

Participants self-reported their pain for each location where they felt it with a score of 1 to 10 before wearing a bracelet. They self-reported their pain again after wearing a bracelet for one day, three days, seven days, 14 days, 21 days and 28 days. Researchers were interested in both the change in the self-reported pain score for the location of greatest pain and the change in the sum of the pain scores for all self-reported painful locations.

Both groups reported significant improvement in pain. However, researchers found no difference in the amount of self-reported pain relief between the group wearing the ionized bracelets and the group wearing the placebo bracelets. The study authors conclude that the equivalent, subjective improvement in pain scores calls into question the true benefit of using an ionized bracelet.

Principal investigator Dr. Robert Bratton, from the Department of Family Medicine, says the study was important because so many patients are interested in alternative medicine. "We need to look at what our patients are doing for their various problems," he says, "and undertake objective, controlled studies to prove whether or not these treatments are beneficial."

The study authors say that although their goal was not to assess the effectiveness of placebos, their results did support the benefit of placebos in the treatment of pain. They also note that 80 percent of the 409 participants who answered an initial survey question about the use of ionized bracelets stated they believed the bracelets can reduce joint or muscle pain.

The study was conducted between 2000-2001. It won the Florida Academy of Family Physicians first-place award for research in October. Mayo Clinic Proceedings is a peer-reviewed and indexed general internal medicine journal, published for more than 75 years by Mayo Foundation, with a circulation of 130,000 nationally and internationally.

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Mayo Clinic is a multispecialty medical clinic in Jacksonville, Fla. The staff includes 328 physicians working in more than 40 specialties to provide diagnosis, treatment and surgery. Patients who need hospitalization are admitted to nearby St. Luke's Hospital, a 289-bed Mayo facility. Mayo Clinics also are located in Rochester, Minn., and Scottsdale, Ariz. Visit <http://www.mayoclinic.org/news/> for all the news from Mayo Clinic.

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